

Food and Drug Administration, HHS

§ 558.4

to obtain and use the VFD drug in or on an animal feed to treat the client's animals only in accordance with the directions for use approved or indexed by the Food and Drug Administration (FDA). A veterinarian may issue a VFD only if a valid veterinarian-client-patient relationship exists, as defined in § 530.3(i) of this chapter.

(8) A "medicated feed" means a Type B medicated feed as defined in paragraph (b)(3) of this section or a Type C medicated feed as defined in paragraph (b)(4) of this section.

(9) For the purposes of this part, a "distributor" means any person who distributes a medicated feed containing a VFD drug to another distributor or to the client-recipient of the VFD.

(10) An "animal production facility" is a location where animals are raised for any purpose, but does not include the specific location where medicated feed is made.

(11) An "acknowledgment letter" is a written communication provided to a distributor by a consignee who is not the ultimate user of medicated feed containing a VFD drug. An acknowledgment letter affirms that the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD, and will not ship such feed to another dis-

tributor without receiving a similar written acknowledgment letter.

[51 FR 7392, Mar. 3, 1986, as amended at 52 FR 2682, Jan. 26, 1987; 54 FR 51386, Dec. 15, 1989; 56 FR 19268, Apr. 26, 1991; 64 FR 63206, Nov. 19, 1999; 65 FR 76929, Dec. 8, 2000; 72 FR 69130, Dec. 6, 2007]

§ 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(c) The use of Type B and Type C medicated feeds shall also conform to the conditions of use provided for in subpart B of this part and in § 558.15 of this chapter.

(d) This paragraph identifies each drug by category, the maximum level of drug in Type B medicated feeds, and the assay limits for the drug in Type A medicated articles and Type B and Type C medicated feeds, as follows:

CATEGORY I

Drug	Assay limits percent ¹ type A	Type B maximum (200x)	Assay limits percent ¹ type B/C ²
Aklomide	90-110	22.75 g/lb (5.0%)	85-120.
Amprolium with Ethopabate	94-114	22.75 g/lb (5.0%)	80-120.
Bacitracin methylene disalicylate	85-115	25.0 g/lb (5.5%)	70-130.
Bacitracin zinc	84-115	5.0 g/lb (1.1%)	70-130.
Bambermycins	90-110	800 g/ton (0.09%)	80-120/70-130.
Buquinolate	90-110	9.8 g/lb (2.2%)	80-120.
Chlortetracycline	85-115	40.0 g/lb (8.8%)	80-115/70-130.
Coumaphos	95-115	6.0 g/lb (1.3%)	80-120.
Decoquinat	90-105	2.72 g/lb (0.6%)	80-120.
Dichlorvos	100-115	33.0 g/lb (7.3%)	90-120/80-130.
Diclazuril	90-110	182 g/t (0.02%)	85-115/70-120.
Efrotomycin	94-113	1.45 g/lb (0.32%)	80-120.
Erythromycin (thiocyanate salt)	85-115	9.25 g/lb (2.04%)	<20g/ton 70-115/150-50->20g/ton 75-125.
Iodinated casein	85-115	20.0 g/lb (4.4%)	75-125.
Laidlomycin propionate potassium	90-110	1 g/lb (0.22%)	90-115/85-115.
Lasalocid	95-115	40.0 g/lb (8.8%)	Type B (cattle and sheep): 80-120; Type C (all): 75-125.
Lincomycin	90-115	20.0 g/lb (4.4%)	80-130.
Melengestrol acetate	90-110	10.0 g/ton (0.0011%)	70-120.

CATEGORY I—Continued

Drug	Assay limits percent ¹ type A	Type B maximum (200x)	Assay limits percent ¹ type B/C ²
Monensin	85–115	40.0 g/lb (8.8%)	Chickens, turkeys, and quail: 75–125; Cattle: 5–10 g/ton 80–120; Cattle: 10–30 g/ton 85–115; Goats: 20 g/ton 85–115; Liq. feed: 80–120.
Narasin	90–110	7.2 g/lb (1.6%)	85–115/75–125.
Nequinat	95–112	1.83 g/lb (0.4%)	80–120.
Niclosamide	85–120	225g/lb (49.5%)	80–120.
Nystatin	85–125	5.0 g/lb (1.1%)	75–125.
Oleandomycin	85–120	1.125 g/lb (0.25%)	<11.25 g/ton 70–130; >11.25 g/ton 75–125.
Oxytetracycline	90–120	20.0 g/lb (4.4%)	75–125/65–135.
Penicillin	80–120	10.0 g/lb (2.2%)	65–135.
Poloxalene	90–110	54.48 g/lb (12.0%)	Liq. feed: 85–115.
Ractopamine	85–105	2.46 g/lb (0.54%)	80–110/75–125.
Salinomycin	95–115	6.0 g/lb (1.3%)	80–120.
Semduramicin (as semduramicin sodium)	90–110	2.27 g/lb (0.50%)	80–110
Semduramicin (as semduramicin sodium biomass)	90–110	2.27 g/lb (0.50%)	80–120
Tiamulin	113.4 g/lb, 100–108 5 and 10 g/1b, 90–115	3.5 g/lb (0.8%)	90–115.
Tylosin	80–120	10.0 g/lb (2.2%)	75–125.
Virginiamycin	85–115	10.0 g/lb (2.2%)	70–130.
Zoalene	92–104	11.35 g/lb (2.5%)	85–115.

¹ Percent of labeled amount.² Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

CATEGORY II

Drug	Assay limits percent ¹ Type A	Type B maximum (100x)	Assay limits percent ¹ Type B/C ²
Amprolium	94–114	11.35 g/lb (2.5%)	80–120.
Apramycin	88–112	7.5 g/lb (1.65%)	80–120.
Arsanilate sodium	90–110	4.5 g/lb (1.0%)	85–115/75–125.
Arsanilic acid	90–110	4.5 g/lb (1.0%)	85–115/75–125.
Carbadox	90–110	2.5 g/lb (0.55%)	75–125.
Carbarsone	93–102	17.0 g/lb (3.74%)	85–115.
Clopidol	94–106	11.4 g/lb (2.5%)	90–115/80–120.
Famphur	100–110	5.5 g/lb (1.21%)	90–115/80–120.
Fenbendazole	93–113	8.87 g/lb (1.96%)	75–125
Florfenicol	90–110	Swine feed: n/a	Swine feed: 85–115
.....		Catfish feed: n/a	Catfish feed: 80–110
.....		Salmonid feed: n/a	Salmonid feed: 80–110
.....		Catfish feed: n/a	Catfish feed: 80–110
Halofuginone hydrobromide	90–115	272.0 g/ton (.03%)	75–125.
Hygromycin B	90–110	1,200 g/ton (0.13%)	75–125.
Ivermectin	95–105	1,180 g/ton (0.13%)	80–110.
Levamisole	85–120	113.5 g/lb (25%)	85–125.
Maduramicin ammonium	90–110	545 g/ton (.06%)	80–120.
Morantel tartrate	90–110	66.0 g/lb (14.52%)	85–115.
Neomycin	80–120	7.0 g/lb (1.54%)	70–125.
Oxytetracycline	80–120	10.0 g/lb (2.2%)	65–135.
Neomycin sulfate	80–120	100 g/lb (22.0%)	70–125.
Nicarbazin (granular)	90–110	5.675 g/lb (1.25%)	85–115/75–125
Narasin	90–110	5.675 g/lb (1.25%)	85–115/75–125
Nicarbazin (powder)	98–106	5.675 g/lb (1.25%)	85–115/80–120
Nitarosone	90–110	8.5 g/lb (1.87%)	85–120.
Nitromide	90–110	11.35 g/lb (2.5%)	80–120.
Sulfanitran	85–115	13.6 g/lb (3.0%)	75–125.
Nitromide	90–110	11.35 g/lb (2.5%)	85–115.
Sulfanitran	85–115	5.65 g/lb (1.24%)	75–125.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.

CATEGORY II—Continued

Drug	Assay limits percent ¹ Type A	Type B maximum (100x)	Assay limits percent ¹ Type B/C ²
Novobiocin	85–115	17.5 g/lb (3.85%)	80–120.
Pyrantel tartrate	90–110	36 g/lb (7.9%)	75–125.
Robenidine	95–115	1.5 g/lb (0.33%)	80–120.
Ronnel	85–115	27.2 g/lb (6.0%)	80–120.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Aklomide	90–110	11.35 g/lb (2.5%)	85–120.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Clopidol	94–106	11.35 g/lb (2.5%)	80–120.
Bacitracin methylene disalicylate.	85–115	5.0 g/lb (1.1%)	70–130.
Roxarsone	90–110	2.275 g/lb (0.5%)	85–120.
Monensin	90–110	5.5 g/lb (1.2%)	75–125.
Sulfadimethoxine	90–110	5.675 g/lb (1.25%)	85–115/75–125.
Ormetoprim (5/3)	90–110	3.405 g/lb (0.75%)	85–115.
Sulfadimethoxine	90–110	85.1 g/lb (18.75%)	85–115/75–125.
Ormetoprim (5/1)	90–110	17.0 g/lb (3.75%)	85–115.
Sulfaethoxyypyridazine	95–105	50.0 g/lb (11.0%)	85–115.
Sulfamerazine	85–115	18.6 g/lb (4.0%)	85–115.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Chlortetracycline	85–115	10.0 g/lb (2.2%)	85–125/70–130.
Penicillin	85–115	5.0 g/lb (1.1%)	85–125/70–130.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Chlortetracycline	85–115	10.0 g/lb (2.2%)	85–125/70–130.
Sulfamethazine	85–115	10.0 g/lb (2.2%)	80–120.
Tylosin	80–120	10.0 g/lb (2.2%)	75–125.
Sulfanitran	85–115	13.6 g/lb (3.0%)	75–125.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Sulfanitran	85–115	13.6 g/lb (3.0%)	75–125.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Roxarsone	90–110	2.715 g/lb (0.60%)	85–120.
Sulfanitran	85–115	13.6 g/lb (3.0%)	75–125.
Aklomide	90–110	11.2 g/lb (2.5%)	85–120.
Roxarsone	90–110	2.27 g/lb (0.5%)	85–120.
Sulfaquinoxaline	98–106	11.2 g/lb (2.5%)	85–115.
Sulfathiazole	85–115	10.0 g/lb (2.2%)	80–120.
Chlortetracycline	85–125	10.0g/lb (2.2%)	70–130.
Penicillin	80–120	5.0 g/lb (1.1%)	70–130.
Thiabendazole	94–106	45.4 g/lb (10.0%)	>7% 85–115; <7% 90–110.
Tilmicosin	90–110	18.2 g/lb (4.0%)	85–115.
Zilpaterol	90–110	680 g/t (0.075%)	80–110/75–115

¹ Percent of labeled amount.² Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limit, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

(e) When drugs from both categories are in combination, the Category II requirements will apply to the combination drug product.

[51 FR 7392, Mar. 3, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.4, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 558.5 Requirements for liquid medicated feed.

(a) *What types of liquid medicated feeds are covered by this section?* This section

covers the following types of liquid medicated feed:

(1) Type B feed that is intended for further manufacture of other medicated feeds (§ 558.3(b)(3)) or:

(2) Type C feed that is intended for the following:

(i) Further manufacture of another Type C feed, or

(ii) Top-dressing (adding on top of the usual ration) (§ 558.3(b)(4)).

(b) *How is liquid free-choice medicated feed regulated?* Liquid free-choice medicated feed is covered by this section and by § 510.455.